

REMARKS

I. INTRODUCTION

Originally filed drawings have been replaced with new Figs. 1-21 which are provided herewith as formal drawings on separate Replacement Sheet. Claims 185, 188 and 218 have been cancelled above, without prejudice. In addition, claims 103, 112, 123, 124, 127, 130, 131, 142, 151-155, 158-161, 170, 179, 186, 187, 197, 199, 212, 213, 215, 217, 223, 232, 237 and 302-306 have been amended above to remove minor informalities therefrom, but not for any reasons relating to patentability thereof. Accordingly, claims 103-184, 186, 187, 189-217, 219-237 and 302-306 are now under consideration in the present application. Provided above, please find a claim listing indicating the current amendments to the previously-pending claims and claim cancellations on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully submitted that no new matter has been added.

II. INFORMATION DISCLOSURE STATEMENT

In the Office Action, the Examiner confirms that the receipt of the information and referenced submitted with the Information Disclosure Statements filed for the above referenced application, and entry thereof into the application. Applicants appreciate the consideration of all submitted materials by the Examiner.

However, the Examiner then states that the number of references and materials listed in the submissions that accompanied the previously-submitted Information Disclosure Statements by Applicants "make it difficult to determine whether or not any of the references, or parts of the references, are material to applicants' claimed invention. It is noted that applicants, in their several IDS submissions, do not

indicate any particular reference or parts of references which they deem 'material' to the patentability of the pending claims under 37 CFR 1.56(b)." (Office Action, p. 2, Ins. 14-17).

It is well established that Applicants are only required to disclose to the U.S. Patent and Trademark Office (the "Patent Office") "all information known to ... [all] individual[s identified in 37 C.F.R. 1.56(a)] to be material to patentability ... [of the claims of the application as defined in 37 C.F.R. 1.56]." 37 C.F.R. § 1.56(a). There is no requirement in this section or any other section of 37 C.F.R. to specifically identify which references (and/or parts thereof) Applicants deem to be material to patentability of the claims pending in the above-identified application. Indeed, while 37 C.F.R. § 1.56(a) provides that "[t]here is no duty to submit information which is not material to the patentability of any existing claim," there is nothing in this section which precludes the submission of any information which may not be material to the patentability of any pending claims in the subject application.

Clearly, Applicants are under no known duty to specifically identify to the Patent Office which references (and/or portions thereof) are material to the patentability of any pending claim of this application. Indeed, Applicants clearly complied with the requirements set forth in 37 C.F.R. § 1.56 by providing to the Patent Office all references which may relate to the claims of the above-referenced application, whether they are material or immaterial to the patentability of any of the pending claims. It appears that the Examiner is inappropriately seeking to impart an additional duty on Applicants where no such duty legally exists.

Next, the Examiner refers to *J.P. Steven & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, *cert. denied*, 106 S.Ct. 73(1973) as describing one of the standards for an

inequitable conduct before the Patent Office. However, this case has absolutely nothing to do with the situation when all references and information known to Applicants have been cited to the Patent Office, and relates to a case when a material reference was not cited to the Patent Office. The present situation is completely different, and indeed factually opposite to the *J.P. Stevens* case. The Examiner, apparently improperly using the holding of this case, again attempts to impose additional burdens on Applicants by requesting that if Applicants are “aware of any cited reference from among the information disclosures of ... [previous IDS submission] that are ‘material,’ applicants should make that reference known to the examiner.” (Office Action, p. 3, Ins. 1-2).

However, the *J.P. Stevens* case provide absolutely no support for the Examiner’s proposition that Applicants should explicitly state which submitted are “material” to the patentability of any pending claim of the present application. As stated above, Applicants have already submitted all references that are known to Applicants and those individuals identified in 37 C.F.R. § 1.56(a) which may be relevant to the claims of the present application. Applicants assert that there is no legal duty, either via 37 C.F.R. or pursuant to any case law, that requires Applicants to make the specific identification requested by the Examiner. Applicants complied with all requirements under 37 C.F.R. § 1.56 to provide the submission as set forth therein, and pursuant to 37 C.F.R. §§ 1.97 and 1.98.

Finally, the Examiner points to *In re Multidistrict-Litig. Involving Forst Patent*, 540 F.2d 601, 604 and other similar cases as providing that “misrepresentation is material if it makes it impossible to the Patent Office fairly to access [the patent] application against the prevailing statutory criteria.” Then, based on this case, the Examiner contends that “the submission of voluminous documents in the instant

information disclosure statements (here in access of 80 documents) make it difficult, and likely impossible, for the Patent Office to fairly assess applicants' [sic] application against the prevailing statutory criteria." Office Action, p. 3, Ins. 3-10).

Applicants respectfully assert that *In re Multidistrict-Litig. Involving Forst Patent* case relied on by the Examiner again address completely different situation from that of the present application. In the cited case, there was a "misrepresentation" that made by applicants of the subject application, and the case addressed when such "misrepresentation" was material. In the present situation, **there is no "misrepresentation" provided to the Patent Office**, as Applicants submitted the information known to them and all individuals identified in 37 C.F.R. § 1.56(a). Simply because Applicants did not or even required to state that any reference (or part thereof) is material (as Applicants are clearly authorized to do under the statutory law and case law of the United States), it can in no way be said that such submission is a "misrepresentation."

Further, because Applicants submitted a large number of references and pieces of information, such fact does not relieve the duty on the Patent Office to diligently assess each such reference as its applicability to the pending claims of the above-identified application. Applicants submitted all reference and information for the present application in full compliance with the laws of the United States and 37 C.F.R. to appropriately bring such references to the attention of the Patent Office. With such task accomplished successfully, the Patent Office has a duty to determine the applicability of such references to the pending claims, and inform Applicants of the same. This duty cannot be removed when there are a large number of submitted references and information.

Thus, Applicants assert that any the above-referenced statement by the Examiner regarding the alleged impropriety of the previously-submitted Information Disclosure Statements for the present application are inappropriate, and should be withdrawn.

III. OBJECTION TO THE DRAWINGS SHOULD BE WITHDRAWN

In the Office Action, the Examiner objected to the drawings due to minor informalities. As the Examiner shall ascertain, new Figs. 1-21 are submitted herewith on "Replacement" sheets to substitute these figures for the drawings originally filed in this application. Accordingly, the objection to the drawings should be withdrawn.

IV. OBJECTIONS TO THE CLAIMS SHOULD BE WITHDRAWN

Claims 103, 112, 123, 124, 127, 131, 142, 151-154, 159, 170, 179, 186, 197, 212, 213, 223, 232 and 303-306 stand objected to due to minor informalities. As the Examiner shall ascertain, these claims have been amended above to remove any such informalities. Accordingly, these objections to claims are now moot, and should therefore be withdrawn.

V. REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

Claims 120-122, 131-158, 185, 204 and 306 stand rejected under 35 U.S.C. § 112, first paragraph as being allegedly non-enabling. Claims 160, 161, 187, 188, 216 and 302 stand rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite.

As an initial matter, claims 185 and 188 have been cancelled above, without prejudice. Accordingly, the rejections of these claims under 35 U.S.C. § 112 are now moot, and should be withdrawn.

With respect to the rejections of claims 120, 131, 158, 204 and 306, and the claims which depend therefrom, under 35 U.S.C. § 112, first paragraph as being allegedly non-enabling, Applicants respectfully disagree and traverse this rejection at least for the following reasons. In particular, the Examiner points to the entire recitation of each of these claims, and asks “[h]ow are these two phase differences created and how do two separate detectors detect the two different phase differences, but detect a common frequency component?” (Office Action, p. 9, Ins. 11-13). Then, the Examiner contends that “applicant’s specification fails to adequately disclose ... [the claimed] limitation.” (*Id.*)

However, the recited subject matter of these claims, i.e., “a common one of the frequency components” is clearly understood by those having ordinary skill in the art as a wavelength of the electro-magnetic radiation (e.g., light) - in other words, at least two of the detectors can detect the same wavelength. In particular, as clearly described in the specification of the present application,

“For example, but not by way of limitation, as shown in Fig. 9, light from the reference arm 400 and sample arm 402 is incident on a grating 404 at slightly different angles and reflected and focused onto a linear N x M photo detector array 406. Along the N direction (column) of the array, wavelength is encoded. Along the M direction (row) of the array, the interference pattern of the sample and reference arm at a particular wavelength is recorded. Since sample and reference arm light were incident at slightly different angles, a pattern of interference maxima and minima will be present in the column direction. Balanced detection can be implemented by subtracting diode signals that are exactly out of phase with respect to the maxima and minima pattern. Alternatively, balanced detection can be implemented by measuring the amplitude of the interference pattern in the column direction which may be accomplished

by subtracting the maxima or the interference pattern from the minima of the interference pattern along the column. An alternative embodiment for balanced detection is combining the reference and sample arm light 400, 402 to produce two outputs that have interference signals with a p phase shift between them. This may be accomplished by taking both output ports of a beam splitter or other beam-recombining element. The two signals may then be detected separately and subtracted. Since the signals that contain the interference terms are shifted by p in phase, these terms add constructively upon the operation of subtraction. The portion of signal that contains RIN, however, cancels upon subtraction. The subtraction operation can occur for all M elements and be conducted in the analog or digital domain. If subtraction is performed in the analog domain, the bandwidth of the signal is reduced by a factor of 2, preferably decreasing specified parameters of the digitization and data transfer across the computer bus.

An example of such balanced detection is shown in Fig 10, which is described more fully hereinbelow. The balance detection outputs are subtracted to generate a balanced signal that cancels RIN."

(Specification of the underlying International Application PCT/US03/02349, page 19, line 18 through page 20, line 20; also see Figures 9, 10 and 12 thereof).

Thus, as described in this exemplary portion of Applicants' specification, the reference and sample arm lights are combined by a 50/50 splitter (e.g., element 712 shown in Figure 10 and unlabeled 50/50 splitter immediately before balanced detection outputs 114). Such 50/50 splitter may have, e.g., two outputs both of which can carry the interference between sample and reference light. Due to the characteristics of the 50/50 splitter, as understood by those having ordinary skill in the art, the interference between the sample and reference arm lights may be 180 degree out of phase between these two outputs. For example, the balanced detection can exploit 180 degree out of phase.

Thus, the specification of the present application provides abundant support for those having ordinary skill in the art to enable the subject matter recited in claims 120, 131, 158, 204 and 306, and the claims which depend therefrom.

Accordingly, for at least the reasons presented herein above, the 35 U.S.C. § 112, first paragraph rejection of claims 120-122, 131-158, 185, 204 and 306 should therefore be withdrawn.

Turning to the rejection of claims 160, 161, 187, 216 and 302 under 35 U.S.C. § 112, second paragraph. While Applicants believe that these claims are surely definite in the prior form, as the Examiner shall ascertain, these claims have been amended above to remove minor informalities therefrom to expedite the prosecution of this application, but not due to any reasons relating to patentability thereof. Accordingly, the 35 U.S.C. § 112, second paragraph rejection of claims 160, 161, 187, 216 and 302 should therefore be withdrawn.

VI. REJECTION UNDER 35 U.S.C. § 101 SHOULD BE WITHDRAWN

Claims 130, 158, 185 and 215 stand rejected under 35 U.S.C. § 101 as being allegedly directed to non-patentable subject matter. While the Examiner confirms that these claims provide useful and concrete results, it is alleged that they are not tangible. The Examiner bases for this allegation on purportedly problematic recitation of “enabling at least one detection of at least one portion of at least one of the frequency components ...” as previously recited in these claims, and contends that this step “has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized.” (Office Action, p. 11, last paragraph to p. 12, ln. 2).

As an initial manner, it appears that the Examiner first agrees that the claim provides a useful result, but then states that it is not useful. Then, the Examiner alleges that the specific recited feature is not tangible.

While Applicants respectfully disagree with the Examiner's allegations, claims 130, 158, 185 and 215 have been amended above to the term "enabling" with the term "causing." Accordingly, Applicants respectfully assert that there can be no doubt that the "causing at least one detection of at least one portion of at least one of the frequency components ..." as now recited in these claims clearly provides a useful, concrete and tangible result in full compliance with the requirements of 35 U.S.C. § 101 and the legal precedent.

Accordingly, the 35 U.S.C. § 101 rejection of claims 130, 158, 185 and 215 should be withdrawn.

VII. REJECTIONS UNDER 35 U.S.C. §102 SHOULD BE WITHDRAWN

Claims 103-119, 123-130, 159, 162-186¹, 189-216, 219-237, 303 and 305 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 7,006,231 issued to Ostrovsky et al. (the "Ostrovsky Patent"). Claims 159, 167-170 and 173-177 finally rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,134,003 issued to Tearney et al. (the "Tearney Patent").

As an initial matter, claim 158 has been cancelled without prejudice. Accordingly, the 35 U.S.C. § 102(e) rejection of this claims is now moot, and should therefore be withdrawn. Further, Applicants respectfully assert that the Ostrovsky Patent fails to disclose the subject matter recited in amended independent claims 103, 130, 159, 186, 215, 237, 303 and 305, and the claims which depend therefrom. In

¹ While the Examiner did not specifically mention claim 186 as being rejected under 35 U.S.C. § 102(e) as being anticipated by the Ostrovsky Patent, it appears that based on the discussion of this claim in the Office Action, the Examiner intended to reject claim 186 in such manner. Accordingly, for the purposes of this response, Applicants shall treat claim 186 as being rejected by the Ostrovsky Patent under 35 U.S.C. § 102(e), and proceed accordingly.

addition, Applicants respectfully assert that the Tearney Patent fails to disclose the subject matter recited in amended independent claim 159, and the claims which depend therefrom.

Thus, Applicants respectfully request the 35 U.S.C. §§ 102(b) and 102(e) rejections of the claims as provided above to be withdrawn for at least the reasons set forth herein below.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

A. Rejection based on Ostrovsky Patent

The Ostrovsky Patent relates to a diffraction grating-based interferometric systems for use in optical coherence tomography. (See Ostrovsky Patent, col. 1, lns 16-19). As shown in FIG. 3a of the Ostrovsky Patent, the diffraction grating-based fiber optic interferometric system 100 includes a light source 102 optically coupled to a fiber optic beam splitter (50/50 splitter) 104 by an optical fiber 106. An optical fiber 108 is optically coupled to the fiber optic beam splitter and to a focusing lens 110. An optical fiber 111 is also optically coupled to the fiber optic beam splitter 104 such that light entering the beam splitter from the optical fiber 108 is coupled into the optical fiber 110. The optical fiber 111 is further optically coupled to a first collimator 112. Another optical fiber 114 is optically coupled to the first beam splitter 104 and to a second collimator 116. The optical fibers 108 and 110 comprise first and second parts of a sample arm,

respectively, of the interferometric system 100. The optical fiber 114 comprises a reference arm of the system 100. (See *id.*, col. 7, Ins. 1-17).

As described in the Ostrovsky Patent, light from the light source 102 passes through the fiber optic beam splitter 104 and is split into a sample light beam and a reference light beam. The sample light beam is directed into the optical fiber 108 of the first part of the sample arm and the reference light beam is directed into the optical fiber 114 of the reference arm. The sample light beam is focused by the focusing lens 110 onto a sample of interest 119, which may be tissue within a body cavity, for example. Light scattered by the sample is focused by the focusing lens 110 to form a second sample light beam and is coupled back into the optical fiber 108 of the sample arm. That light passes back through the first beam splitter 104, where the light beam is split again. (See *id.*, col. 7, Ins. 17-35).

The second collimator 116 of the Ostrovsky Patent collimates the reference light beam and directs the reference light beam onto a diffraction grating 118 at an angle α . The diffraction grating 118 introduces an optical path difference to the reference light beam and reflects the diffracted reference light beam onto a second, open space beam splitter 120. The first collimator 112 also collimates the second sample light beam and directs it onto the second beam splitter 120. (See *id.*, col. 7, Ins. 36-43).

Accordingly, the diffraction grating 118 of the Ostrovsky Patent receives and separates the spectrum of only the light provided from the reference arm, and not any light from the sample or the combination of the sample light and the reference light. (See *id.*, Fig. 3A).

Applicants' invention, as recited in amended independent claim 103, relates to an apparatus for optical imaging, which comprises, *inter alia*:

a device receiving at least one first electro-magnetic radiation from a sample and at least one second electro-magnetic radiation from a non-reflective reference;

at least one spectral separating unit which separates spectrum of at least one of the first electro-magnetic radiation or a combination of the first and second electro-magnetic radiation into frequency components

Claims 159 and 186 each relates to an apparatus, claims 130 and 215 relate to methods, and claims 303 and 305 relate to probes which recite similar subject matter.

Applicants respectfully assert that the Ostrovsky Patent in no way discloses ***separating spectrum of a first electro-magnetic radiation (received from a sample) or a combination of the first and second electro-magnetic radiation (a combination of radiations received from the sample and a reference) into frequency components***, as recited in amended independent claims 103, 130, 159, 186, 215, 303 and 305 of the above-identified application.

In the Office Action, the Examiner points to the diffraction grating 118 of the Ostrovsky Patent as separating the spectrum of the electro-magnetic radiation provided thereto. (See Office Action, p. 13, 3rd paragraph). However, this diffraction grating 118 only receives the reference light beam from the reference arm, but does not separate the spectrum of the sample light beam (received from the sample arm) or any combination of the sample and reference light beams. (See Ostrovsky Patent, col. 7, lns. 36-43; and Fig. 3A). In contrast, amended independent claims 103, 130, 159, 186, 215, 303 and 305 of the present application specifically recite that the **spectrum of the first electro-magnetic radiation (received from the sample) or the combination of**

the first and second electro-magnetic radiation (e.g., the combination of the radiations received from the sample and the reference) is separated into frequency components, and not that the spectrum of the second electro-magnetic radiation is separated into frequency components.

Further, Applicants' invention, as recited in amended independent claim 216, relates to an apparatus for optical imaging, which comprises, *inter alia*:

a device receiving at least one first electro-magnetic radiation from a first arm and at least one second electro-magnetic radiation from a second arm ... ; [and]

at least one of spectral separating arrangement which separates spectrum of a combination of the first and second electro-magnetic radiations into frequency components

Claim 237 relates to a methods which recites similar subject matter.

Similarly to the arguments provided above, Applicants respectfully assert that the Ostrovsky Patent does not disclose ***separating spectrum of the combination of the first and second electro-magnetic radiation (a combination of radiations received from two arm) into frequency components***, as recited in amended independent claims 216 and 237 of the above-identified application. Again, the Ostrovsky Patent only mentions the application of the reference light beam from the reference arm to the diffraction grating, but has absolutely no disclosure of the separation of the spectrum of the combination of two electro-magnetic radiations from respective two arms.

Accordingly, Applicants respectfully submit that the Ostrovsky Patent does not anticipate the subject matter recited in independent claims 103, 130, 159, 186, 215, 216, 237, 303 and 305 . The claims which depend from such independent claims are also not disclosed by the Ostrovsky Patent for at least the same reasons. Thus,

withdrawal of the rejection of these claims under 35 U.S.C. § 102(e) is respectfully requested.

B. Rejection based on Tearney Patent

The Tearney Patent relates to medical imaging with interferometric detection. (See Tearney Patent, col. 1, Ins. 28-30). As shown in Fig. 16 of the Tearney Patent, two optical radiation sources 602, 603 are utilized. The radiations emitted by these sources 602, 603 are combined in a WDM multiplexer 605 and transmitted to a wavelength independent optical coupler 606 which directs the radiation along an optical path defining the measuring arm 610 including a Faraday circulator 630 and a rotation mechanism 635 coupled to an endoscopic unit 634, and along an optical path defining the reference arm 608, including a phase modulator 624, a Faraday circulator 630, and a dispersion compensation system 626. Light reflected by the reference reflector 612 and structure 614 is combined by the coupler 606 and transmitted to a WDM demultiplexer 620. The output optical signals are input optical signals to two detectors 616, 617. (See *id.*, col. 16, Ins. 39-58).

Applicants' invention, as recited in amended independent claim 159, relates to an apparatus for optical imaging, which comprises, *inter alia*:

a device receiving at least one first electro-magnetic radiation from a sample and at least one second electro-magnetic radiation from a non-reflective reference;

at least one spectral separating unit which separates spectrum of at least one of the first electro-magnetic radiation or a combination of the first and second electro-magnetic radiation into frequency components; [and]

at least one detection arrangement including at least three detectors, each of the detectors configured to detect at least a portion of at least one of the frequency components ...

Applicants respectfully assert that the Tearney Patent in no way discloses **at least one detection arrangement including at least three detectors, each of the detectors configured to detect at least a portion of at least one of the frequency components** , as recited in amended independent claim 159 of the above-identified application. While the Tearney Patent describes the use of two (2) detectors, i.e., the detectors 616, 617, the Tearney Patent does not disclose the use of three (3) or more detectors configured to detect at least a portion of one or more frequency components. (See, *e.g.*, Applicants' specification and Figs. 2 and 6).

Accordingly, the Tearney Patent fails to disclose the subject matter recited in amended independent claims 159, Claims 167-170 and 173-177 which depend from amended independent claim 159 are also not disclosed by the Tearney Patent for at least the same reasons. Thus, withdrawal of the § 102(b) rejection of these claims is respectfully requested.

VIII. CLAIMS NOT REJECTED BASED ON PRIOR ART GROUNDS

Applicants note that independent claims 131, 158, 304 and 306, and dependent claims 120, 160, 187 and 217 were not rejected as being anticipated by either the Ostrovsky Patent or the Tearney Patent. Thus, it is believed that the Examiner intended to confirm that if such claims are amended to overcome the rejections under 35 U.S.C. §§ 101 and/or 112 as discussed in the Office Action, these claims would be deemed allowable.

Accordingly, independent claims 131, 158, 304 and 306 have been amended to overcome the applicable rejections 35 U.S.C. § 101 and/or 35 U.S.C. §

112. Further, dependent claims 120, 160, 187 and 217 have been rewritten to be in independent form to include the subject matter of previously pending claims 103, 159, 186 and 216, respectively, and amended to overcome the applicable rejections 35 U.S.C. § 101 and/or 35 U.S.C. § 112.

Thus, amended independent claims 120, 131, 158, 160, 187, 217, 304 and 306, and claims which depend therefrom are believed to be allowable. Applicants respectfully request a confirmation of such believe by the Examiner in the next communication.

IX. CONCLUSION

In light of the foregoing, Applicants respectfully submit that pending claims 103-184, 186, 187, 189-217, 219-237 and 302-306 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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